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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/577,694	05/22/2000	Anne Sorensen	Novo-029	3706

23650 7590 08/17/2005

NOVO NORDISK, INC.
PATENT DEPARTMENT
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PRINCETON, NJ 08540

EXAMINER

HON, SOW FUN

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 08/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/577,694

Applicant(s)

SORENSEN.ET AL.

Examiner

Sow-Fun Hon

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/13/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Withdrawn Rejections

1. The objections and 35 U.S.C. 103(a) rejections are withdrawn due to Applicant's amendment dated 06/13/05.

New Rejections

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 63-75, 77-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai (US 4,444,330).

Regarding claims 63, 67-68, 73, 77, 80-81, Kasai teaches a stopper which comprises an injection-mouldable blend of 30 to 90 weight % butyl based rubber and up to 30 weight % polyolefin (column 1, lines 45-55) which overlaps the combination of the claimed range of 70-90 % by weight of butyl rubber and 30-10 % by weight of polyolefin (claims 63, 73); and the narrower one of 75-87 % butyl based rubber and 13-25 % by weight of polyolefin (claims 67, 80).

Kasai teaches that the polyolefin is polypropylene or polyethylene, added to improve mouldability (column 1, lines 60-65) (claims 68, 81). Polypropylene and polyethylene are not elastomers, as defined by Applicant's specification (page 5, lines 30-35 and page 8, lines 1-5).

Kasai teaches that the butyl rubber alone is subject to permanent set and cannot provide a stopper for hermetically sealing a medical container (column 2, lines 30-40) thus teaching that a stopper made from a combination of the butyl rubber and another component provides for a hermetically sealed container resulting in a reduced leakage of substances compared to a stopper made from butyl rubber alone.

Kasai teaches that the stopper optionally comprises (may comprise) a filler in the amount of not more than 80 % by weight (column 3, lines 40-55), which means that the claimed range of 10 % by weight or less is encompassed. Kasai teaches that the stopper does not contain additives which might cause elution (column 5, lines 50-60) which is within the claimed range of 1 % by weight or less of additives.

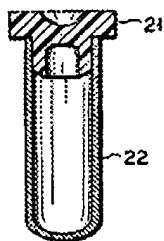
Regarding claim 64-66, Kasai teaches that the butyl rubber is blended with up to 30 % polypropylene or polyethylene (column 1, lines 45-55), the blend is homogenized with heating (kneaded in mixer at 150 °C to 250 °C), and the stopper is injection moulded (column 3, lines 55-65). Injection moulding requires the blend to be fluid, thus injection moulding at 250 °C means that the thermoplastic polypropylene or polyethylene is in the melt. Hence the composition and process steps of stopper manufacture are similar to those described in Applicant's specification (page 2, lines 25-30). Therefore a hardness of 40-80 Shore A (claim 64), of 45-75 Shore A (claim 65), or of 65-75 Shore A (claim 66) is the result of routine experimentation by one of ordinary skill in the art at the time the invention was made, in order to obtain the desired stopper performance.

Regarding claims 69-70, 82-83, the butyl-based rubber is a halogenated one (column 1, lines 50-55) such as a bromobutyl rubber (column 2, line 65).

Regarding claims 71, 84, the butyl-based rubber is at least partially crosslinked (column 1, lines 50-55).

Regarding claims 72, 85, Fig. 5 below shows that the stopper 21 has a substantially circular cross-section.

F I G. 5



Regarding claims 73-74, Kasai teaches a medical container with non-flexible (hard) walls (column 1, lines 10-15). Fig. 5 above shows that the container 22 comprises a distal and a proximal end, and at least one wall defining an interior space for storing liquid blood (column 5, lines 40-50). The term "medical container" means that the contents can be liquid medicament such as liquid infusion solution (column 1, lines 10-15). One of the end portions of the medical container comprises a stopper 21. The composition of the stopper has been described above.

Regarding claim 75, Kasai provides an example of the process comprising mixing the butyl rubber and the thermoplastic polymer to form a stopper material, via heating (kneaded with a mixer) at 150 to 250 °C to homogenize the stopper material and then injecting at preferably 200 to 220 °C to form pellets (column 3, lines 55-60).

Art Unit: 1772

This means that the butyl rubber is heated and the polyolefin is melted during the homogenizing and subsequent pelletizing process. The stopper material is moulded by injection moulding to obtain the stopper (column 3, lines 60-65).

4. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai as applied to claims 63-75 above, and further in view of Rheude (US 2,507,680).

Kasai teaches a stopper comprising an injection-mouldable material made of a butyl based rubber and a polyolefin wherein the polyolefin is not an elastomer, and wherein the butyl-based rubber is present in an amount of 70-90 % by weight and wherein additives are optionally present in an amount not exceeding 1 % by weight and filler are optionally present in an amount less than 10 % by weight and wherein the balance of the material is polyolefin, and wherein the combination of the butyl based rubber and the polyolefin results in a reduced leakage of substances compared to the leakage of substances from a stopper made from a butyl based rubber alone, as described above. Kasai fails to teach a rod, let alone a rod moulded onto the stopper by the means of two-component injection moulding.

Rheude teaches a stopper for a container (bottle), which has a pusher rod 6 (column 2, lines 1-5). It can be seen in Fig 3 that the pusher rod results in the stopper being completely inserted into the neck of the container.

Anyone who has tried to shove a rubber stopper into a bottle neck knows how difficult it is to push it in completely. Rheude has shown that it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have attached a pusher rod to the stopper of Kasai, in order to facilitate insertion of the

Art Unit: 1772

stopper into the neck of the container. Coordination of the push-stop motions is difficult unless the pusher rod and the stopper are integral. It would therefore have been obvious to one of ordinary skill in the art at the time the invention was made, to have moulded the rod of Rheude onto the stopper during the injection moulding step in the process of Kasai, which step would then have been termed two component injection moulding, to provide an integral rod-on-stopper combination in order to obtain better push-stop coordination.

Response to Arguments

5. Applicant's arguments with respect to claims 63-76 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1772

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Hon.
Sow-Fun Hon

08/09/05


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

8/15/05